serum levels of calcium and phosphorus are normal or near normal for end stage renal disease patients. At the end of the second 12-week treatment period (during which time 1α—OH-vitamin D_2 treatment is suspended and replaced by placebo therapy), mean serum PTH values markedly increase, reaching pretreatment levels. This study demonstrates that: (1) 1α—OH-vitamin D_2 is effective in reducing serum PTH levels, and (2) 1α—OH-vitamin D_2 is safer than currently used therapies, despite its higher dosages and concurrent use of high levels of oral calcium phosphate binder.

The foregoing examples demonstrate that 1α—OH-vitamin D_2 is effective in preventing or restoring the loss of bone mass or bone mineral content while being substantially less toxic than 1α,25—$(OH)_2$-vitamin D_3 and 1α—OH-vitamin D_3. It is to be understood that although the foregoing examples detail the use of 1α—OH-vitamin D_2, other compounds within the scope of the claims may be readily utilized in the treatment of this invention with essentially equivalent results. For example, 1α,24(S)—$(OH)_2$-vitamin D_2 shows activity equivalent to 1α,24(R)—$(OH)_2$-vitamin D_3 and is also significantly less toxic than its vitamin D_3 counterpart. Also included within the scope of the claims would be administration of effective dosages of the analog of formula (I) in conjunction with administration of other hormones or other agents which have been shown to stimulate bone formulation in subjects experiencing or tending toward loss of bone mass or bone mineral content.

Such hormones or other agents may include conjugated estrogens or their equivalents, calcitonin, biphosphonates, calcium supplements, cobalamin, pertussis toxin and boron. Possible dose ranges for these co-administered agents are provided in Table 1.

TABLE 1

Possible Oral Dose Ranges for Various Agents Co-Administered With 1α-Hydroxyvitamin D_2

Agent	Dose Ranges		
	Broad	Preferred	Most Preferred
Conjugated Estrogens or Equivalent (mg/day)	0.3–5.0	0.4–2.4	0.6–1.2
Sodium Fluoride (mg/day)	5–150	30–75	40–60
Calcitonin (IU/day)	5–800	25–500	50–200
Biphosphonates (mg/day)	50–2000	100–1500	250–1000
Calcium Supplements (mg/day)	250–2500	500–1500	750–1000
Cobalamin (μg/day)	5–200	20–100	30–50
Pertussis Toxin (mg/day)	0.1–2000	10–1500	100–1000
Boron (mg/day)	0.10–3000	1–250	2–100

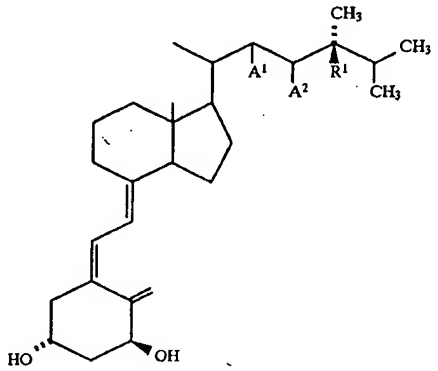
Although the above examples detail dosage by mouth, it is to be understood that the compounds can also be administered in alternative fashions, including intranasally, transdermally, intrarectally, intravaginally, subcutaneously, intravenously, and intramuscularly.

In summary, the present invention provides therapeutic methods for lowering blood levels of parathyroid hormone which are secondary to end stage renal disease. The method in accordance with the present invention has significantly less resultant hypercalcemia and hyperphosphatemia.

While the present invention has now been described and exemplified with some specificity, those skilled in the art will appreciate the various modifications, including variations, additions, and omissions, that may be made in what has been described. Accordingly, it is intended that these modifications also be encompassed by the present invention and that the scope of the present invention be limited solely by the broadest interpretation that lawfully can be accorded the appended claims.

We claim:

1. A method for lowering or maintaining lowered serum parathyroid hormone in human patients suffering from hyperparathyroidism, comprising: administering to said patients an effective amount of a vitamin D analog to lower and maintain lowered serum parathyroid hormone levels, said analog comprising formula (I):



(I)

wherein A^1 and A^2 are either hydrogen or a carbon-carbon double bond between C—22 and C—23; and R^1 is hydrogen or hydroxyl provided that when A^1 and A^2 are a double bond, R^1 is hydrogen.

2. The method according to claim 1, wherein said analog of formula (I) is 1α—OH-vitamin D_2; 1α—OH-vitamin D_4; or 1α,24(R)—$(OH)_2$-vitamin D_4.

3. The method of claim 1 wherein said analog comprises a dosage of 1 to about 100 μg/week.

4. The method of claim 1 wherein said analog, in solution, in a liquid vehicle ingestible by and nontoxic to said patients, is administered orally in encapsulated form.

5. The method of claim 1 wherein said analog is administered in combination with at least one agent characterized by said agent's ability to reduce loss of bone mass, or bone mineral content in patients.

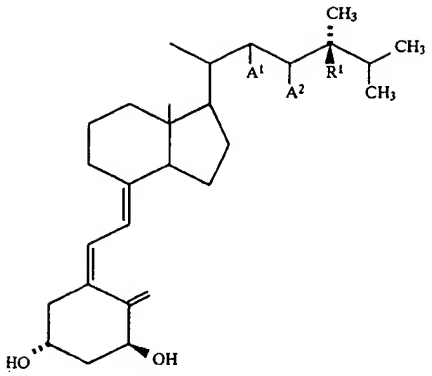
6. The method of claim 5 wherein said agent includes other vitamin D compounds, conjugated estrogens, sodium fluorides, biphosphonates, cobalamin, pertussin toxin or boron.

7. The method of claim 1, wherein said administration of said analog is parenteral.

8. The method of claim 7 wherein said administration is by subcutaneous, intramuscular, or intravenous injection, nasopharyngeal or mucosal absorption, or transdermal absorption.

9. The method of claim 1 wherein said administration of said analog is nonparenteral.

10. A method for achieving an effect in a patient comprising administering to the patient an effective amount of a vitamin D analog of formula (I):



(I)

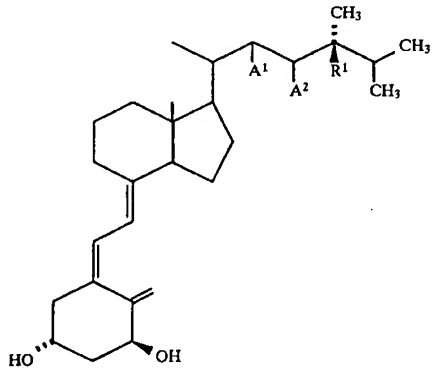
wherein A^1 and A^2 are either hydrogen or a carbon-carbon double bond between C—22 and C—23: and R^1 is hydrogen or hydroxyl provided that when A^1 and A^2 are a double bond, R^1 is hydrogen, and wherein the effect is lowering or maintaining lowered serum parathyroid hormone levels, and thus decreasing loss of bone mass or bone mineral content.

11. The method of claim 2, wherein said analog is 1α—OH-vitamin D_2.

12. The method of claim 1, wherein said analog is co-administered with a calcium phosphate binder.

13. A method of treating a human to alleviate or prevent the pathological effects of hyperparathyroidism, wherein the method comprises administering to the human in need thereof a vitamin D analog selected from the group consisting of 1α—OH-vitamin D_2, 1α—OH-vitamin D_4 and 1α,24 (R)—$(OH)_2$-vitamin D_4 wherein said analog is administered to the human in an amount sufficient to lower or maintain lowered serum parathyroid hormone levels in the human to thereby alleviate or prevent the effects.

14. A method for lowering or maintaining lowered serum parathyroid hormone in human patients suffering from secondary hyperparathyroidism, comprising: administering to said patients an effective amount of a vitamin D analog to lower and maintain lowered serum parathyroid hormone levels, said analog comprising formula (I):



(I)

wherein A^1 and A^2 are either hydrogen or a carbon-carbon double bond between C—22 and C—23; and R^1 is hydrogen or hydroxyl provided that when A^1 and A^2 are a double bond, R^1 is hydrogen.

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